

§ 423.553 Effect of leasing of a PDP sponsor's facilities.

(a) *General effect of leasing.* If a PDP sponsor leases all or part of its facilities to another entity, the other entity does not acquire PDP sponsor status under section 1860D–12(b) of the Act.

(b) *Effect of lease of all facilities.* (1) If a PDP sponsor leases all of its facilities to another entity, the contract terminates.

(2) If the other entity wishes to participate in Medicare as a PDP sponsor, it must apply for and enter into a contract in accordance with § 423.502.

(c) *Effect of partial lease of facilities.* If the PDP sponsor leases part of its facilities to another entity, its contract with CMS remains in effect while CMS surveys the PDP sponsor to determine whether it continues to be in compliance with the applicable requirements and qualifying conditions specified in subpart K of this part.

Subpart M—Grievances, Coverage Determinations, Redeterminations, and Reconsiderations**§ 423.558 Scope.**

(a) This subpart sets forth the requirements relating to the following:

(1) Part D plan sponsors with respect to grievances, coverage determinations, and redeterminations.

(2) Part D IRE with respect to reconsiderations.

(3) Part D enrollees' rights with respect to grievances, coverage determinations, redeterminations, and reconsiderations.

(b) The requirements regarding reopenings, ALJ hearings, MAC review, and Judicial review are set forth in subpart U of this chapter.

[74 FR 65363, Dec. 9, 2009]

§ 423.560 Definitions.

As used in this subpart, unless the context indicates otherwise—

Appeal means any of the procedures that deal with the review of adverse coverage determinations made by the Part D plan sponsor on the benefits under a Part D plan the enrollee believes he or she is entitled to receive, including delay in providing or approv-

ing the drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage, as defined in § 423.566(b). These procedures include redeterminations by the Part D plan sponsor, reconsiderations by the independent review entity, ALJ hearings, reviews by the Medicare Appeals Council (MAC), and judicial reviews.

Appointed representative means an individual either appointed by an enrollee or authorized under State or other applicable law to act on behalf of the enrollee in filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process. Unless otherwise stated in this subpart, the appointed representative has all of the rights and responsibilities of an enrollee in filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process, subject to the rules described in part 422, subpart M of this chapter.

Drug Use means an enrollee is receiving the drug in the course of treatment, including time off if it is part of the treatment.

Enrollee means a Part D eligible individual who has elected or has been enrolled in a Part D plan.

Grievance means any complaint or dispute, other than one that involves a coverage determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D plan sponsor, regardless of whether remedial action is requested.

Other prescriber means a health care professional other than a physician who is authorized under State law or other applicable law to write prescriptions.

Physician has the meaning given the term in section 1861(r) of the Act.

Projected value of a Part D drug or drugs includes any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year. Projected value includes enrollee co-payments, all expenditures incurred after an enrollee's expenditures exceed the initial coverage limit, and expenditures paid by other entities.